IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

B. BRAUN MELSUNGEN AG & B. BRAUN MEDICAL INC.,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 1:09-CV-00347
TERUMO MEDICAL CORPORATION & TERUMO CORPORATION,	)	
Defendants.	)	

TERUMO MEDICAL CORPORATION'S AND TERUMO CORPORATION'S FIRST AMENDED ANSWER AND COUNTERCLAIMS TO COMPLAINT

Defendants Terumo Medical Corporation ("Terumo Medical") and Terumo Corporation ("Terumo") answer the Complaint of Plaintiffs B. Braun Melsungen AG ("B. Braun") and B. Braun Medical Inc. ("B. Braun Medical"), filed on May 13, 2009 (the "Complaint"), which alleges patent infringement of United States Patent No. 7,264,613 (the "'613 Patent").

THE PARTIES

1. Paragraph 1 does not require a response by Defendants. To the extent that paragraph 1 is deemed to require a response, Defendants lack sufficient information to form a belief as to the truth of the allegations and on that basis deny all allegations in paragraph 1.

2. Paragraph 2 does not require a response by Defendants. To the extent that paragraph 2 is deemed to require a response, Defendants lacks sufficient information to form a belief as to the truth of the allegations and on that basis deny all allegations in paragraph 2.

3. Admit.

4. Admit.

5. Defendants admit that the Complaint purports to state a cause of action for patent infringement arising under the provisions of the Patent Laws of the United States, Title 35, United States Code. Terumo Medical admits that it is subject to personal jurisdiction in Delaware for purposes of this action only. Terumo is not disputing personal jurisdiction in Delaware for purposes of this action only. Defendants deny that they have committed acts of infringement in this District by advertising, marketing, offering for sale, and selling their products in this District.

VENUE

6. Defendants admit that venue is proper and that they are not disputing personal jurisdiction in this District for this action only. Defendants deny that they have committed acts of infringement in this District.

INFRINGEMENT ALLEGATIONS OF U.S. PATENT NO. 7,264,613

7. Defendants admit that a copy of the '613 Patent that purports to be entitled "Spring Clip Safety IV Catheter" and issued on September 4, 2007 was attached as Exhibit A to the Complaint. Defendants lack sufficient information to form a belief as to the truth of the remaining allegations in paragraph 7 and therefore deny all remaining allegations of paragraph 7.

8. Defendants deny that they are infringing the '613 Patent through the manufacture, use, sale, offer for sale, and/or importation into the United States of safety IV catheters under the trade name "Surshield® Safety I.V. Catheter."

9. Defendants deny that they are infringing the '613 Patent and further deny that Plaintiffs are entitled to any injunctive relief.

10. Defendants deny that they are infringing the '613 Patent or that their actions are causing irreparable harm or monetary damage to Plaintiffs. Defendants further deny that Plaintiffs are entitled to any injunctive relief.

11. Defendants lack sufficient information to form a belief as to the truth of the allegations in paragraph 11. However, Defendants specifically deny that any alleged infringement has been or continues to be willful.

12. Unless expressly admitted herein, Defendants deny each and every allegation in each and every paragraph of the Complaint.

AFFIRMATIVE DEFENSES

As further answer and as affirmative defenses, Terumo Medical and Terumo allege the following:

FIRST AFFIRMATIVE DEFENSE – NON-INFRINGEMENT

13. Neither Terumo Medical nor Terumo have infringed and do not infringe, directly or indirectly, any valid claim of the '613 Patent.

SECOND AFFIRMATIVE DEFENSE – INVALIDITY

14. Upon information and belief, Terumo Medical and Terumo allege that one or more of the claims of the '613 Patent are invalid for failure to satisfy the conditions of patentability set forth in the Patent Laws of the United States, Title 35, United States Code, and specifically as set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

THIRD AFFIRMATIVE DEFENSE – PROSECUTION HISTORY ESTOPPEL

15. Upon information and belief, Terumo Medical and Terumo allege that Plaintiffs are barred or limited from recovery in whole or in part by the doctrine of prosecution history estoppel.

FOURTH AFFIRMATIVE DEFENSE – FAILURE TO MARK

16. Upon information and belief, Terumo Medical and Terumo allege that Plaintiffs are barred or limited from recovery in whole or in part by the failure to mark as required under the provisions of the Patent Laws of the United States, Title 35, United States Code, and in particular, 35 U.S.C. § 287.

FIFTH AFFIRMATIVE DEFENSE – FAILURE TO STATE A CLAIM

17. Upon information and belief, Terumo Medical and Terumo allege that the Complaint filed by Plaintiffs fails to state a claim upon which relief can be granted.

SIXTH AFFIRMATIVE DEFENSE – DENIAL OF COST

18. Upon information and belief, Terumo Medical and Terumo allege that Plaintiffs are not entitled to any costs in this litigation pursuant to 35 U.S.C. § 288.

SEVENTH AFFIRMATIVE DEFENSE – UNENFORCEABILITY

19. Terumo Medical and Terumo allege that the '613 Patent is unenforceable for inequitable conduct due to the failure of Braun[1] and its attorneys to disclose material information to the U.S. Patent Office that they received from at least Mr. Donald McLees ("McLees") and possibly others. The material information relates to: (1) ways to modify a needle used in a safety IV catheter, such as by crimping the needle or "press flaring" the needle so that the safety clip that covers the sharp end of the needle is prevented from sliding off the sharp end of the needle by the crimp or "press flare"; and (2) methods and techniques for crimping or "press flaring" needles used in safety IV catheters and for designing and manufacturing the same. This information will be collectively referred to as "the McLees Ideas for Safety IV Catheters." As set forth herein, at least one individual with a duty to disclose material information, the

[1] Braun refers collectively to B. Braun and B. Braun Medical throughout the Seventh Affirmative Defense – Unenforceability section.

prosecuting attorney, Mr. William Christie ("Christie"), of the law firm of Christie, Parker & Hale, LLP possessed the McLees Ideas for Safety IV Catheters. However, neither Christie nor anybody else provided this information to the Patent Office.

20. Terumo Medical and Terumo also allege that the '613 Patent is unenforceable due to inequitable conduct due to actions Braun and its attorneys took to suggest to the Patent Office that the concept of crimping or "press flaring" a needle in an IV catheter, and claims directed thereto, were entitled to a priority date before August 14, 2000.

The Work of McLees in the Field of Safety Needles and Safety IV Catheters

21. McLees is an inventor of various medical devices with a dual degree in mechanical and industrial engineering. He has obtained numerous patents in the area of needle guards. These patents include U.S. Patent Nos. 5,059,180 entitled "Automatic Needle Tip Guard" (the '180 patent); 5,135,504 entitled "Needle Tip Guard" (the '504 patent); 5,183, 468 entitled "Snap Ring Needle Guard" (the '468 patent); and 5,334,158 entitled "Automatic Needle Tip Guard For Standard Hypodermic Needles" (the '158 patent).

22. McLees became aware in approximately early 1989 of the need for safety IV catheter sets due to the AIDS crisis. His work in this area led to a needle guard designed to fit inside of an IV catheter hub that operates automatically when the needle is withdrawn from the patient. This work is reflected in McLees' '504 patent. The '504 patent includes an enlarged diameter shoulder that engages the guard and retains the guard on the tip of the needle as the needle is withdrawn.

23. McLees began contacting manufacturers of catheters in the United States in the fall of 1989 in an effort to interest them in the technology of the '504 patent. One of the catheter

manufacturers McLees contacted at that time was Becton Dickinson because they were a large manufacturer of safety needles and safety IV catheters.

24. McLees sent a copy of his then pending '504 patent application to Becton Dickinson on or about September 19, 1989. Subsequently, McLees had additional conversations and communications with Becton Dickinson regarding the technology of the '504 patent. However, in about late October 1989, Becton Dickinson communicated to McLees that it was not interested in the technology of the '504 patent because it believed the design was too complex and could not be manufactured at a reasonable cost.

25. In November and December of 1989, subsequent to and as a result of Becton Dickinson indicating it was not interested in the technology of the '504 patent because it believed the technology was too complex and could not be manufactured at a reasonable cost, McLees began working on different and better ways to modify a needle for a safety IV catheter and to hold a needle guard on the needle. The focus of this work was to develop ways to modify the needle and manufacture safety IV catheters that would provide a simple, low cost, and easy to manufacture design.

26. It was this work by McLees in November and December 1989 that resulted in the McLees Ideas for Safety IV Catheters.

27. McLees' ideas and inventions are reflected in at least the following:

- Notes from November and December 1989 relating to McLees' idea to crimp or press flare the needle in a safety IV catheter set; (Ex. A)
- Notes from January 1990 reflecting, among other things, McLees' calculations relating to the negligible effect that crimping or press flaring would have on the insertion characteristics of a needle; (Ex. B)

- A letter from McLees to a Mr. Crawford at Becton Dickinson dated February 26, 1990, providing a prototype of McLees' needle design and explaining, among other things, that crimping or press flaring the needle only required a simple operation to slightly spread the side of the needle once the protective clip is positioned on the needle shaft in order to hold the guard on the needle; (Ex. C) and
- A document entitled "Needle Tip Guard Fabrication Suggestions From The Inventor" that describes manufacturing and assembly procedures and includes drawings. (Ex. D)

The notes identified above are from McLees' inventor's notebook. It has been his practice to make such notes in his inventor's notebook and maintain such an inventor's notebook. The notes and other documents identified above are collectively referred to as "the McLees Ideas Documents."

28. McLees communicated much of the results of this work, including the McLees Ideas Documents, to at least Becton Dickinson in various communications from November 1989 to February 1990.

Braun Obtains Information From McLees

29. Upon information and belief, Christie was an attorney with the law firm of Christie, Parker & Hale LLP who worked on various matters for Braun, including litigations and litigation related matters.

30. Upon information and belief, Christie was involved in some capacity in the defense of an action filed by Becton Dickinson against Braun in 1999, *Becton Dickinson Co, et al v. B Braun Medical*, USDC - D.UT – 2:99-cv-00987.

31. Upon information and belief, as part of his work for Braun, Christie spoke with McLees around late 1999 or early 2000. Christie contacted McLees by telephone to discuss McLees' work in the field of needles and safety IV catheters and his interactions and communications with Becton Dickinson. Christie also requested that McLees send him information and documents that McLees had previously provided to Becton Dickinson relating to the McLees Ideas for Safety IV Catheters.

32. McLees initially faxed a limited set of documents to Christie that included communications that were previously exchanged on his behalf with Becton Dickinson.

33. McLees subsequently sent additional documents and information, including at least the McLees Ideas Documents, to Christie shortly after Christie first contacted him around late 1999 or early 2000.

34. McLees subsequently worked with another attorney representing Braun in the Becton Dickinson litigation, Mr. Ed Donovan, to draft a declaration describing his interactions with Becton Dickinson and the McLees Ideas for Safety IV Catheters. A copy of the McLees' declaration is attached as Exhibit E.

The '613 Patent Family

35. The '613 Patent was filed on May 23, 2003 and issued on September 4, 2007. The '613 Patent is a continuation of U.S. application no. 09/638,641, filed on August 14, 2000, now U.S. Patent No. 6,616,630 ("the '630 Patent"). The '630 Patent is a continuation-in-part of U.S. application no. 09/183,697, filed on October 30, 1998, now patent no. 6,287,278 ("the '278 Patent.") The '630 Patent alleges priority back through a chain of continuation-in-part applications to U.S. application no. 08/915,148 ("the '148 Application"). Copies of the '613

Patent, the '630 Patent, the '278 Patent, and the '148 Application are attached as Exhibits F, G, H, and I respectively.

36. The '148 Application was filed and prosecuted by the law firm of Hopgood, Calimafde, Kalil & Judlowe. The '148 Application contained 13 pages in its specification and Figures 1A and 1B through Figures 6A and 6B, for a total of 12 figures. (Each of the figures illustrated the protective clip in a ready position within the catheter hub as the "A" figure and in a protected position covering the sharp end of the needle as the "B" figure.) Neither the '148 Application nor the '278 Patent immediately preceding the '630 Patent in the '613 Patent family include any disclosure or claims directed to either crimped or press flared needles or crimping techniques.

37. On May 2, 2000, the law firm of Christie, Parker & Hale, LLP, took over the prosecution of the '613 Patent family (Ex. J). Various attorneys from Christie, Parker & Hale, LLP were listed on the power of attorney, including Christie (Ex. K). Christie was also identified as the attorney to whom all correspondence should be sent (Ex. K).

Braun Incorporates Crimping Into Its '613 Patent Family Specification

38. Within months of Christie receiving the McLees Ideas for Safety IV Catheters and the McLees Ideas Documents, on August 14, 2000, Christie, Parker & Hale, LLP, on behalf of Braun, filed the '630 patent adding new matter and changing other wording:

- Figures 18 and 19 were added;
- New disclosure related to Figures 18 and 19 describing the needle in an IV catheter along with manufacturing techniques (Ex. G, '630 Patent, col. 13, lns. 9-24); and

> As shown in FIGS. **18** and **19**, the crimp **138** formed in the needle **16** preferably defines a pair of generally opposed, outwardly extending bulges **138***a* in the needle and also defines a pair of generally opposed, inwardly extending depressions **138***b*, which are disposed generally orthogonally with respect to the bulges **138***a*. The bulges **138***a* define a crimp **138** having a width, dimension W, which is small enough to facilitate movement of the needle **16** within the catheter **24**, as shown in FIG. **14**, and which is too large to pass through the central opening **134** formed in the end wall **126** of the needle guard **120**, as discussed above.
>
> The crimp **138** may be formed by any contemporary crimping process, such as those processes wherein two jaws of a vise or crimper come together so as to squeeze the needle **16** in a manner which forms the depressions **138***b* of FIG. **19**, thereby consequently also forming the bulges **138***a*.

- Braun replaced the word "bulge" with the word "crimp" at various locations in the specification.[2]

Braun Adds Claims to Crimping

39. On May 29, 2002, approximately 21 months after filing the '630 Patent, Christie, on behalf of Braun, signed and entered a Preliminary Amendment that added claims to a crimped needle. A crimped needle was included in at least claims 53, 54, and 58 that were added by the preliminary amendment. A copy of the preliminary amendment filed by Christie is attached as Exhibit L.

40. After submitting the preliminary amendment, Christie filed an amendment to correct the named inventors related to the '630 application in order to add Mark Wynkoop as an inventor. The stated reason for the change in inventorship was that the claims added in the preliminary amended necessitated the correction to the named inventors. A copy of the Amendment filed by Christie is attached as Exhibit M.

41. The '613 Patent is a continuation of the '630 Patent and includes the same disclosure added by Braun to the '630 Patent. Christie remained an attorney of record in the

[2] The replacement occurred in at least eight locations.

prosecution of the '613 Patent and was the individual identified to direct correspondence to regarding the application. A copy of the declaration Braun filed with its application resulting in the '613 Patent is attached as Exhibit N.

42. From the date the '613 Patent was filed, Braun maintained claims that included a crimped needle. Issued claims 1, 8, 17, and 28 of the '613 Patent recite a crimped needle as part of a safety IV catheter set and are collectively referred to as "the Crimping Claims."

Elements of Inequitable Conduct

43. At a minimum, Braun's attorney Christie was in possession of at least the McLees Ideas Documents that relate to techniques for crimping or press flaring a needle used in a safety IV catheter set and techniques to easily and inexpensively manufacture safety IV catheter sets that include a crimped or press flared needle. Despite possession of the McLees Ideas Documents, neither Braun nor Christie submitted the McLees Ideas Documents to the U.S. Patent Office during prosecution of the '613 Patent. As a result, the McLees Ideas Documents were neither known by or available to the U.S. Patent Office during its examination of the application resulting in the '613 Patent.

44. There is a substantial likelihood that a reasonable examiner would have considered the McLees Ideas Documents as important in deciding whether to allow the Crimping Claims to issue pursuant to 35 U.S.C. § 102(f) and/or § 102(g). The McLees Ideas Documents demonstrate that crimping or "press flaring" a needle used in a safety IV catheter was McLees' idea and McLees developed simple and cost effective techniques for manufacturing safety IV catheters. As a result, the McLees Ideas Documents were material to the prosecution of the Crimping Claims of the '613 Patent.

45. Alternatively, the McLees Ideas Documents are material regarding the Crimping Claims because they establish a *prima facie* case of unpatentability under 35 U.S.C. § 102(f) and/or § 102(g), or refute or are inconsistent with the inventors declarations that they invented the subject matter of the Crimping Claims. Further, the McLees Ideas Documents are not cumulative of any other information of record in the prosecution of the '613 Patent regarding at least the issues of derivation of the invention or proper inventorship under 35 U.S.C. § 102(f) and/or § 102(g) with respect to the Crimping Claims.

46. Upon information and belief, at least Christie must have known that a reasonable examiner would have considered the McLees Ideas Documents material and, therefore, his decision not to provide those documents to the Patent Office demonstrates an intent to deceive the Patent Office. Further, Terumo is seeking the deposition of Christie and will question him on this issue.

47. Upon information and belief, at least Christie and potentially others were involved in the affirmative actions Braun and its attorneys took to cause the Patent Office to believe that the concept of crimping or press flaring a needle in an IV catheter, and claims directed thereto, were entitled to a priority date before August 14, 2000. These affirmative actions, including submitting misleading Figs. 18 and 19 and the corresponding description, demonstrate an intent to deceive the Patent Office. Further, Terumo is seeking the deposition of Christie and will question him on this issue.

48. As a result of at least Christie's failure on behalf of Braun to disclose the McLees Ideas Documents to the U.S. Patent Office during prosecution of the application resulting in the '613 Patent, Braun withheld material information from the U.S. Patent Office with the intent to deceive the U.S. Patent Office as to the proper inventorship of the '613 Patent.

49. As a result of at least Christie's affirmative actions to cause the Patent Office to believe that the concept of crimping a needle in an IV catheter, and claims directed thereto, were entitled to a priority date before August 14, 2000, Braun affirmatively misled the U.S. Patent Office with an intent to deceive as to the priority date for certain claims in the '613 Patent.

COUNTERCLAIMS

Defendants and counterclaim plaintiffs Terumo Medical Corporation ("Terumo Medical") and Terumo Corporation ("Terumo"), by and through its undersigned attorneys, plead the following counterclaims against Plaintiffs and counterclaim defendants B. Braun Melsungen AG ("B. Braun") and B. Braun Medical Inc. ("B. Braun Medical"):

1. Terumo Medical is a Delaware corporation with a principal place of business located in Somerset, New Jersey.

2. Terumo is a Japanese company with a principal place of business located in Shibuya-ku, Tokyo, Japan.

3. Upon information and belief, counterclaim defendant B. Braun is a German company with its principal place of business at Carl-Braun Strasse 1, 34212 Melsungen, Germany.

4. Upon information and belief, counterclaim defendant B. Braun Medical is a corporation organized under the laws of Pennsylvania with its principal place of business at 824 Twelfth Avenue, Bethlehem, Pennsylvania, 18018.

5. Counterclaim defendants allege in their Complaint that B. Braun has continuously held title in, and B. Braun Medical has had exclusive rights to sell the patented invention in the United States, from issuance of the '613 Patent to the present.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*. and the Declaratory Judgment Act, § 2201, *et seq*.

7. This Court has subject matter jurisdiction over Terumo Medical's and Terumo's counterclaims pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

8. B. Braun and B. Braun Medical have submitted to the personal jurisdiction and venue of this Court.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400.

COUNT I
(Declaratory Judgment of Non-Infringement)

10. Terumo Medical and Terumo incorporate by reference in this cause of action all of the allegations set forth in paragraphs 1 through 9 of their Counterclaims.

11. B. Braun and B. Braun Medical have filed suit against Terumo Medical and Terumo alleging in the Complaint that Terumo Medical and Terumo have infringed the '613 Patent. As a result of these allegations and the filing of the lawsuit, Terumo Medical and Terumo have a reasonable apprehension that B. Braun and B. Braun Medical will continue to assert the '613 Patent against Terumo Medical and Terumo.

12. Terumo Medical and Terumo have not and do not infringe any claim of the '613 Patent, either literally or under the doctrine of equivalents.

13. An actual case and controversy exists between counterclaim plaintiffs, Terumo Medical and Terumo, and counterclaim defendants, B. Braun and B. Braun Medical, regarding Terumo Medical's and Terumo's non-infringement of the '613 Patent, which is within the jurisdiction of this Court.

14. By reason of the foregoing, Terumo Medical and Terumo are entitled to a declaratory judgment by this Court that Terumo Medical and Terumo do not infringe the '613 Patent, including noninfringement of the '613 Patent literally and/or under the doctrine of equivalents.

COUNT II
(Declaratory Judgment of Invalidity)

15. Terumo Medical and Terumo incorporate by reference in this cause of action all of the allegations set forth in paragraphs 1 through 14 of their Counterclaims.

16. B. Braun and B. Braun Medical have filed suit against Terumo Medical and Terumo alleging in the Complaint that Terumo Medical and Terumo have infringed the '613 Patent. As a result of these allegations and the filing of the lawsuit, Terumo Medical and Terumo have a reasonable apprehension that B. Braun and B. Braun Medical will continue to assert the '613 Patent against Terumo Medical and Terumo.

17. The claims of the '613 Patent are invalid for failure to comply with the U.S. Patent Laws, 35 U.S.C. §§ 1, *et seq.*, including without limitation §§ 101, 102, 103 and/or 112.

18. An actual case and controversy exists between counterclaim plaintiffs, Terumo Medical and Terumo, and counterclaim defendants, B. Braun and B. Braun Medical, regarding the '613 Patent that is within the jurisdiction of this Court.

19. Based upon the foregoing, Terumo Medical and Terumo are entitled to a declaratory judgment from the Court that the claims of the '613 Patent are invalid.

COUNT III
(Declaratory Judgment of Unenforceability)

20. Terumo Medical and Terumo incorporate by reference in this cause of action all of the allegations set forth in paragraphs 1 through 19 of their Counterclaims.

21. Braun[3] filed suit against Terumo Medical and Terumo alleging in the Complaint that Terumo Medical and Terumo have infringed the '613 Patent. As a result of these allegations and the filing of the lawsuit, Terumo Medical and Terumo have a reasonable apprehension that Braun will continue to assert the '613 Patent against Terumo Medical and Terumo.

22. Terumo Medical and Terumo allege that the '613 Patent is unenforceable for inequitable conduct due to the failure of Braun and its attorneys to disclose material information to the U.S. Patent Office that they received from at least Mr. Donald McLees ("McLees") and possibly others. The material information relates to: (1) ways to modify a needle used in a safety IV catheter, such as by crimping the needle or "press flaring" the needle so that the safety clip that covers the sharp end of the needle is prevented from sliding off the sharp end of the needle by the crimp or "press flare"; and (2) methods and techniques for crimping or "press flaring" needles used in safety IV catheters and for designing and manufacturing the same. This information will be collectively referred to as "the McLees Ideas for Safety IV Catheters." As set forth herein, at least one individual with a duty to disclose material information, the prosecuting attorney, Mr. William Christie ("Christie"), of the law firm of Christie, Parker & Hale, LLP possessed the McLees Ideas for Safety IV Catheters. However, neither Christie nor anybody else provided this information to the Patent Office.

23. Terumo Medical and Terumo also allege that the '613 Patent is unenforceable due to inequitable conduct due to actions Braun and its attorneys took to suggest to the Patent Office that the concept of crimping or "press flaring" a needle in an IV catheter, and claims directed thereto, were entitled to a priority date before August 14, 2000.

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[3] Braun refers collectively to B. Braun and B. Braun Medical throughout the Count III (Declaratory Judgment of Unenforceability) section.

The Work of McLees in the Field of Safety Needles and Safety IV Catheters

24. McLees is an inventor of various medical devices with a dual degree in mechanical and industrial engineering. He has obtained numerous patents in the area of needle guards. These patents include U.S. Patent Nos. 5,059,180 entitled "Automatic Needle Tip Guard" (the '180 patent); 5,135,504 entitled "Needle Tip Guard" (the '504 patent); 5,183, 468 entitled "Snap Ring Needle Guard" (the '468 patent); and 5,334,158 entitled "Automatic Needle Tip Guard For Standard Hypodermic Needles" (the '158 patent).

25. McLees became aware in approximately early 1989 of the need for safety IV catheter sets due to the AIDS crisis. His work in this area led to a needle guard designed to fit inside of an IV catheter hub that operates automatically when the needle is withdrawn from the patient. This work is reflected in McLees' '504 patent. The '504 patent includes an enlarged diameter shoulder that engages the guard and retains the guard on the tip of the needle as the needle is withdrawn.

26. McLees began contacting manufacturers of catheters in the United States in the fall of 1989 in an effort to interest them in the technology of the '504 patent. One of the catheter manufacturers McLees contacted at that time was Becton Dickinson because they were a large manufacturer of safety needles and safety IV catheters.

27. McLees sent a copy of his then pending '504 patent application to Becton Dickinson on or about September 19, 1989. Subsequently, McLees had additional conversations and communications with Becton Dickinson regarding the technology of the '504 patent. However, in about late October 1989, Becton Dickinson communicated to McLees that it was not interested in the technology of the '504 patent because it believed the design was too complex and could not be manufactured at a reasonable cost.

28. In November and December of 1989, subsequent to and as a result of Becton Dickinson indicating it was not interested in the technology of the '504 patent because it believed the technology was too complex and could not be manufactured at a reasonable cost, McLees began working on different and better ways to modify a needle for a safety IV catheter and to hold a needle guard on the needle. The focus of this work was to develop ways to modify the needle and manufacture safety IV catheters that would provide a simple, low cost, and easy to manufacture design.

29. It was this work by McLees in November and December 1989 that resulted in the McLees Ideas for Safety IV Catheters.

30. McLees' ideas and inventions are reflected in at least the following:

- Notes from November and December 1989 relating to McLees' idea to crimp or press flare the needle in a safety IV catheter set; (Ex. A)
- Notes from January 1990 reflecting, among other things, McLees' calculations relating to the negligible effect that crimping or press flaring would have on the insertion characteristics of a needle; (Ex. B)
- A letter from McLees to a Mr. Crawford at Becton Dickinson dated February 26, 1990, providing a prototype of McLees' needle design and explaining, among other things, that crimping or press flaring the needle only required a simple operation to slightly spread the side of the needle once the protective clip is positioned on the needle shaft in order to hold the guard on the needle; (Ex. C) and

- A document entitled "Needle Tip Guard Fabrication Suggestions From The Inventor" that describes manufacturing and assembly procedures and includes drawings. (Ex. D)

The notes identified above are from McLees' inventor's notebook. It has been his practice to make such notes in his inventor's notebook and maintain such an inventor's notebook. The notes and other documents identified above are collectively referred to as "the McLees Ideas Documents."

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Braun Obtains Information From McLees

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37. McLees subsequently worked with another attorney representing Braun in the Becton Dickinson litigation, Mr. Ed Donovan, to draft a declaration describing his interactions with Becton Dickinson and the McLees Ideas for Safety IV Catheters. A copy of the McLees' declaration is attached as Exhibit E.

The '613 Patent Family

38. The '613 Patent was filed on May 23, 2003 and issued on September 4, 2007. The '613 Patent is a continuation of U.S. application no. 09/638,641, filed on August 14, 2000, now U.S. Patent No. 6,616,630 ("the '630 Patent"). The '630 Patent is a continuation-in-part of U.S. application no. 09/183,697, filed on October 30, 1998, now patent no. 6,287,278 ("the '278 Patent.") The '630 Patent alleges priority back through a chain of continuation-in-part applications to U.S. application no. 08/915,148 ("the '148 Application"). Copies of the '613 Patent, the '630 Patent, the '278 Patent, and the '148 Application are attached as Exhibits F, G, H, and I respectively.

39. The '148 Application was filed and prosecuted by the law firm of Hopgood, Calimafde, Kalil & Judlowe. The '148 Application contained 13 pages in its specification and Figures 1A and 1B through Figures 6A and 6B, for a total of 12 figures. (Each of the figures illustrated the protective clip in a ready position within the catheter hub as the "A" figure and in a protected position covering the sharp end of the needle as the "B" figure.) Neither the '148

Application nor the '278 Patent immediately preceding the '630 Patent in the '613 Patent family include any disclosure or claims directed to either crimped or press flared needles or crimping techniques.

40. On May 2, 2000, the law firm of Christie, Parker & Hale, LLP, took over the prosecution of the '613 Patent family (Ex. J). Various attorneys from Christie, Parker & Hale, LLP were listed on the power of attorney, including Christie (Ex. K). Christie was also identified as the attorney to whom all correspondence should be sent (Ex. K).

Braun Incorporates Crimping Into Its '613 Patent Family Specification

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- Figures 18 and 19 were added;
- New disclosure related to Figures 18 and 19 describing the needle in an IV catheter along with manufacturing techniques (Ex. G, '630 Patent, col. 13, lns. 9-24); and

> As shown in FIGS. **18** and **19**, the crimp **138** formed in the needle **16** preferably defines a pair of generally opposed, outwardly extending bulges **138***a* in the needle and also defines a pair of generally opposed, inwardly extending depressions **138***b*, which are disposed generally orthogonally with respect to the bulges **138***a*. The bulges **138***a* define a crimp **138** having a width, dimension W, which is small enough to facilitate movement of the needle **16** within the catheter **24**, as shown in FIG. **14**, and which is too large to pass through the central opening **134** formed in the end wall **126** of the needle guard **120**, as discussed above.
>
> The crimp **138** may be formed by any contemporary crimping process, such as those processes wherein two jaws of a vise or crimper come together so as to squeeze the needle **16** in a manner which forms the depressions **138***b* of FIG. **19**, thereby consequently also forming the bulges **138***a*.

- Braun replaced the word "bulge" with the word "crimp" at various locations in the specification.[4]

Braun Adds Claims to Crimping

42. On May 29, 2002, approximately 21 months after filing the '630 Patent, Christie, on behalf of Braun, signed and entered a Preliminary Amendment that added claims to a crimped needle. A crimped needle was included in at least claims 53, 54, and 58 that were added by the preliminary amendment. A copy of the preliminary amendment filed by Christie is attached as Exhibit L.

43. After submitting the preliminary amendment, Christie filed an amendment to correct the named inventors related to the '630 application in order to add Mark Wynkoop as an inventor. The stated reason for the change in inventorship was that the claims added in the preliminary amended necessitated the correction to the named inventors. A copy of the Amendment filed by Christie is attached as Exhibit M.

44. The '613 Patent is a continuation of the '630 Patent and includes the same disclosure added by Braun to the '630 Patent. Christie remained an attorney of record in the prosecution of the '613 Patent and was the individual identified to direct correspondence to regarding the application. A copy of the declaration Braun filed with its application resulting in the '613 Patent is attached as Exhibit N.

45. From the date the '613 Patent was filed, Braun maintained claims that included a crimped needle. Issued claims 1, 8, 17, and 28 of the '613 Patent recite a crimped needle as part of a safety IV catheter set and are collectively referred to as "the Crimping Claims."

[4] The replacement occurred in at least eight locations.

Elements of Inequitable Conduct

46. At a minimum, Braun's attorney Christie was in possession of at least the McLees Ideas Documents that relate to techniques for crimping or press flaring a needle used in a safety IV catheter set and techniques to easily and inexpensively manufacture safety IV catheter sets that include a crimped or press flared needle. Despite possession of the McLees Ideas Documents, neither Braun nor Christie submitted the McLees Ideas Documents to the U.S. Patent Office during prosecution of the '613 Patent. As a result, the McLees Ideas Documents were neither known by or available to the U.S. Patent Office during its examination of the application resulting in the '613 Patent.

47. There is a substantial likelihood that a reasonable examiner would have considered the McLees Ideas Documents as important in deciding whether to allow the Crimping Claims to issue pursuant to 35 U.S.C. § 102(f) and/or § 102(g). The McLees Ideas Documents demonstrate that crimping or "press flaring" a needle used in a safety IV catheter was McLees' idea and McLees developed simple and cost effective techniques for manufacturing safety IV catheters. As a result, the McLees Ideas Documents were material to the prosecution of the Crimping Claims of the '613 Patent.

48. Alternatively, the McLees Ideas Documents are material regarding the Crimping Claims because they establish a *prima facie* case of unpatentability under 35 U.S.C. § 102(f) and/or § 102(g), or refute or are inconsistent with the inventors declarations that they invented the subject matter of the Crimping Claims. Further, the McLees Ideas Documents are not cumulative of any other information of record in the prosecution of the '613 Patent regarding at least the issues of derivation of the invention or proper inventorship under 35 U.S.C. § 102(f) and/or § 102(g) with respect to the Crimping Claims.

49. Upon information and belief, at least Christie must have known that a reasonable examiner would have considered the McLees Ideas Documents material and, therefore, his decision not to provide those documents to the Patent Office demonstrates an intent to deceive the Patent Office. Further, Terumo is seeking the deposition of Christie and will question him on this issue.

50. Upon information and belief, at least Christie and potentially others were involved in the affirmative actions Braun and its attorneys took to cause the Patent Office to believe that the concept of crimping or press flaring a needle in an IV catheter, and claims directed thereto, were entitled to a priority date before August 14, 2000. These affirmative actions, including submitting misleading Figs. 18 and 19 and the corresponding description, demonstrate an intent to deceive the Patent Office. Further, Terumo is seeking the deposition of Christie and will question him on this issue.

51. As a result of at least Christie's failure on behalf of Braun to disclose the McLees Ideas Documents to the U.S. Patent Office during prosecution of the application resulting in the '613 Patent, Braun withheld material information from the U.S. Patent Office with the intent to deceive the U.S. Patent Office as to the proper inventorship of the '613 Patent.

52. As a result of at least Christie's affirmative actions to cause the Patent Office to believe that the concept of crimping a needle in an IV catheter, and claims directed thereto, were entitled to a priority date before August 14, 2000, Braun affirmatively misled the U.S. Patent Office with an intent to deceive as to the priority date for certain claims in the '613 Patent.

53. The '613 Patent is unenforceable due to the inequitable conduct of Braun.

54. An actual case and controversy exists between counterclaim plaintiffs, Terumo Medical and Terumo, and counterclaim defendants, Braun, regarding the '613 Patent that is within the jurisdiction of this Court.

55. Based upon the foregoing, Terumo Medical and Terumo are entitled to a declaratory judgment from the Court that the '613 Patent is unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Terumo Medical and Terumo respectfully request that the Court enter judgment in favor of Terumo Medical and Terumo on the foregoing and enter a judgment granting the following relief:

A. That the Court dismiss B. Braun's and B. Braun Medical's Complaint as to Terumo Medical and Terumo;

B. That the Court dismiss B. Braun's and B. Braun Medical's claims in their entirety, with prejudice, as to Terumo Medical and Terumo;

C. That the Court find that B. Braun and B. Braun Medical are not entitled to any of their requested relief, or any relief whatsoever, as to Terumo Medical or Terumo;

D. That the Court find that B. Braun and B. Braun Medical are not entitled to any costs in this litigation, pursuant to § 288;

E. That the Court find that the claims of the '613 Patent are invalid;

F. That the Court find the '613 Patent is unenforceable;

F. That the Court find that Terumo Medical and Terumo have not infringed any valid, enforceable claims of the '613 Patent, directly or indirectly, under any subsection of 35 U.S.C. § 271;

G. That the Court find this to be an exceptional case entitling Terumo Medical and Terumo to an award of attorneys fees, expenses, and costs pursuant to 35 U.S.C. § 285;

H. That the Court deny any preliminary or permanent injunctive relief sought by B. Braun and/or B. Braun Medical against Terumo Medical or Terumo; and

I. That the Court award Terumo Medical and Terumo such other and further relief as the Court deems just and appropriate.

DEMAND FOR JURY TRIAL

Terumo Medical and Terumo hereby demand a jury trial on all issues triable to a jury.

Dated: December 22, 2009

FISH & RICHARDSON P.C.

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